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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,663	02/08/2002	Charles Larry Bisgaier	5730-C1-01-FJT	4182

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02/12/2003

Warner-Lambert Company  
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EXAMINER

JIANG, SHAOJIA A

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 02/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

10/071,663

Applicant(s)

BISGAIER ET AL.

Examiner

Shaojia A. Jiang

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 November 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,10,21-24 and 27-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,10,21-24 and 27-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

This application is a continuation of Serial No. 09/554994 (now abandoned) which is a 371 of PCT/US98/25495, which claims priority to provisional application Serial No. 60/072,912.

Applicant's preliminary amendment in Paper No. 6, submitted November 13, 2002 in response to the Restriction Requirement of August 27, 2002 in Paper No. 4, is acknowledged. Claims 2-9, 11-20 and 25-26 are cancelled and claims 27-36 are newly submitted. Currently, claims 1, 10, 21-24 and 27-36 are pending in this application.

### ***Election/Restrictions***

Applicant's election without traverse of the invention of the species in claim 33 and 36, in Paper No. 6, submitted November 13, 2002 is acknowledged.

On consideration by the examiner, the specie election requirement is modified to include all compounds of Formula in claim 29 as a single specie, elected by Applicant in Paper No. 6.

It is merely noted for the record that the expression "ACAT inhibitors" in claims 28-36 renders claims 28-36 unclear since the expression "ACAT inhibitors" used to identify/describe particular compounds herein and, accordingly, the identification/description is unclear.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10, 21-24 and 27-36 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claims are drawn to the methods for preventing the onset of Alzheimer's disease. The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApl 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,
- 3) the presence of absence of working examples,
- 4) the nature of the invention,
- 5) the state of the prior art,
- 6) the relative skill of those in the art
- 7) the predictability of the art, and

8) the breadth of the claims.

Nature of the invention: The instant invention pertains to the methods for preventing the onset of Alzheimer's disease.

The state of the prior art: The skilled artisan would view that the treatment to prevent the onset of Alzheimer's disease is highly unlikely.

The predictability or lack thereof in the art: The skilled artisan would view that the treatment to prevent the onset of Alzheimer's disease is highly unpredictable.

The presence or absence of working examples: In the instant case, no working examples are presented in the specification as filed showing how to prevent the onset of Alzheimer's disease.

Therefore, in view of the Wands factors, as discussed above, e.g., the amount of direction or guidance provided, absence of working examples, and the predictability of the art, Applicants fail to provide information sufficient to practice the claimed invention.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 35-36 contain the trademark/trade name ACAT. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of

goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe particular inhibitors herein and, accordingly, the identification/description is indefinite.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 10, 21-24 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Scolnick (WO 95/06470, PTO-892).

Scolnick discloses that statins (known HMG-CoA reductase inhibitors), which are known lower plasma-triglyceride and LDLC levels and increase HDL levels, are useful in methods of treating the onset of Alzheimer's disease. Scolnick also discloses an effective Alzheimer's disease alleviating amount of statins to be administered. See abstract, page 10, and claims 1-25. Thus, Scolnick anticipates claims 1, 10, 21-24 and 27.

Claims 1, 10, 21-24 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by JP8143454 (PTO-892).

JP8143454 discloses that eicosapentaenoic acid (EPA), known to be useful to lower plasma-triglyceride and LDLC levels and increase HDL levels, are useful in

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methods of treating the onset of Alzheimer's disease. See abstract. Thus, JP8143454 anticipates claims 1, 10, 21-24 and 27.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 27-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. (5,491,172, PTO-892) in view of Scolnick (WO 95/06470, PTO-892).

Lee et al. discloses that the instant compounds covered by the formula (I) in the patent lowers plasma-triglyceride and LDLC levels and increases HDL levels, and are useful for treating hypercholesterolemia. See abstract, col.1 lines 18-60, col.2, and claims 15.

Lee et al. does not expressly disclose that the instant claimed compound may be useful in methods of treating the onset of Alzheimer's disease.

Scolnick discloses that statins (HMG-CoA reductase inhibitors), which are known lower plasma-triglyceride and LDLC levels and increase HDL levels, are useful in methods of treating and preventing the onset of Alzheimer's disease. Moreover, Scolnick teaches that the reduction of cholesterol and plasma-triglyceride and LDLC levels may decrease risk of development of Alzheimer's disease and treat vascular

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related diseases such as Alzheimer's disease. See abstract, page 2 lines 16-20, page 10, and claims 1-25.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the instant compounds in methods of treating the onset of Alzheimer's disease herein.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ the instant claimed compounds in methods of treating the onset of Alzheimer's disease since the instant compounds are known to be useful for lowering plasma-triglyceride and LDLC levels and treating hypercholesterolemia. It is also known that the reduction of plasma-triglyceride and LDLC levels may decrease risk of development of Alzheimer's disease and treat vascular related diseases such as Alzheimer's disease. Therefore, one of ordinary skill in the art would have found it obvious to employ the instant claimed compounds in methods of treating the onset of Alzheimer's disease.

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

In view of the rejections to the pending claims set forth above, no claims are allowed.

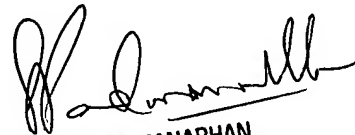
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.



If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

S. Anna Jiang, Ph.D.  
Patent Examiner, AU 1617  
January 30, 2003

  
SREENI PADMANABHAN  
PRIMARY EXAMINER

2/10/03